

**AMENDMENTS TO THE DRAWINGS**

The attached new sheet of drawings includes FIG. 1.

Attachments:        One (1) New Drawing Sheet (Figure 1)

**REMARKS**

**I. Status of the Application**

Claims 9-10 and 12-29 are pending in this application, with claims 9, 12, 14-15, 17-18, 20-21, and 23 being independent.

In the Office Action dated April 17, 2008, ("Office Action"), the Examiner objected to the drawings under 37 C.F.R. § 1.83(a); rejected claims 9-10 and 12-13 under 35 U.S.C. § 112 ¶ 2, as allegedly being indefinite; rejected claims 14, 17, 20, 23, and 26-29 under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 02/076535 ("DCA Design International"); and rejected claims 9-10 and 12-29 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Pub. No. 2002/0052578 ("Moller").

By this amendment, Applicant has amended FIG. 1. Applicant has amended claims 14, 17, and 20. The claim amendments are supported by the originally filed specification and drawings, and no new matter has been entered. Claims 1-8 and 11 have been cancelled. Applicant respectfully requests in light of these amendments and the remarks below that the Examiner withdraw the objection to the drawings and the rejections of remaining claims 9-10 and 12-29, and allow those claims to proceed to issue.

**II. Objections to the Drawings**

The Office Action objects to the drawings under 37 C.F.R. § 1.83(a) for an alleged failure to show the ring gear of the epicyclic gearbox as claimed. Applicant has amended the specification and FIG. 1 to illustrate that the splines 46 may serve as a ring gear of the epicyclic gearbox. No new matter has been added by these

amendments. Therefore, in light of these amendments, Applicant respectfully requests that the objections to the drawings be withdrawn.

### **III. Rejection Under § 112 ¶ 2**

The Office Action rejects claims 9-10 and 12-13 under 35 U.S.C. § 112 ¶ 2 as allegedly being indefinite. The Office Action alleges that “the drug delivery device comprises [the housing, piston rod, dose dial sleeve, and drive sleeve] and not the drive mechanism.” Office Action at 3. Applicant respectfully traverses this rejection.

Claims 9 and 10 recite a “drive mechanism for a drug delivery device” including, *inter alia*, “a housing . . . a piston rod . . . a dose dial sleeve . . . and a drive sleeve.” Claims 12 and 13 recite an “assembly for use in a drug delivery device” including, *inter alia*, “a drive mechanism . . . a housing . . . a piston rod . . . a dose dial sleeve . . . and a drive sleeve.”

Applicant submits that the Office Action incorrectly construes the drive mechanism as something separate and apart from “the housing, piston rod, dose dial sleeve, and drive sleeve.” The specification, however, teaches that all of the features listed may be used to drive the drug delivery device, and thus *comprise* a drive mechanism. Specifically: the gearbox may “releasibly connect[] said dose dial sleeve to said drive sleeve” (¶ 12); the housing may “house, fix, protect, guide, and/or engage with any of the inner components of the drug delivery device” including drive components (¶ 14); the piston rod may receive the “torque from the dose dial sleeve or the dose button” by way of the gearbox (¶ 24); the dose dial sleeve may transmit torque to the drive sleeve or the piston rod by way of the gearbox (¶ 24); and, the drive sleeve may receive the “torque from the dose dial sleeve or the dose button” by way of the

gearbox (¶ 24). Furthermore, in claim 12, although the drive mechanism is listed as a feature separate from the housing, piston rod, dose dial sleeve, and drive sleeve, nothing precludes those features from operating together to drive a drug delivery device or be used as an assembly for use in a drug delivery device.

For at least the above reasons, Applicant submits that the Office Action's rejection of claims 9 and 12 (and claims 10 and 13 depending therefrom, respectively) under § 112 ¶ 2 is unsustainable. Accordingly, Applicant respectfully requests that the Examiner withdraw this rejection.

#### **IV. Rejection Under § 102(b) Over DCA Design International**

The Office Action rejects claims 14, 17, 20, 23, and 26-29 as allegedly being anticipated by DCA Design International. Applicant notes that the Office Action rejects the claims under § 102(b), and submits that the reference is not available as prior art under § 102(b). To the extent that the Office Action intended to use § 102(a) as a basis for rejection, Applicant respectfully traverses the rejection.

The Office Action alleges that DCA Design International discloses "a drug injection device comprising a housing [containing] an epicyclic gearbox." Office Action at 4. The Office Action further alleges that DCA Design International discloses "a sun gear (20), multiple planetary gears (24), and a ring gear (26 or the splines of 20)." *Id.*

Claim 14 as amended recites "a second portion of the housing containing a drive mechanism including an epicyclic gearbox and a drive sleeve configured to engage a piston." Amended claim 17 recites "providing a drive mechanism including an epicyclic gearbox in the second portion of the housing; and providing a dose dial sleeve configured to drivingly engage the epicyclic gearbox." Amended claim 20 recites

“providing a pen-type housing [and] an epicyclic gearbox in the second portion of the pen-type housing.” Amended claim 20 finds support at least in FIGS. 1-6 and paragraphs 1 and 13 of the specification as originally filed.

Applicant submits that nothing in DCA Design International teaches or suggests all of the features of amended claims 14, 17, and 20 (and dependent claims 23 and 26-29). While DCA Design International discloses a housing 2 and gears 16, 20, and 24; DCA Design International fails to disclose at least a “drive sleeve configured to engage a piston” as recited by amended claim 14. Additionally, DCA Design International fails to disclose at least a “dose dial sleeve” (as recited by amended claim 17) or a “pen-type housing” (as recited by amended claim 20).

For at least the above reasons, Applicant respectfully requests that the Examiner withdraw the rejection of these claims.

#### **V. Rejection Under § 102(b) Over Moller**

The Office Action rejects claims 9-10 and 12-29 as allegedly being anticipated by Moller. The Applicant once again submits that although the Office Action rejects the claims under § 102(b), the reference is not available under § 102(b). To the extent that the Office Action intended to use § 102(a) as a basis for rejection, Applicant respectfully traverses the rejection.

According to the Office Action, Moller allegedly discloses a device comprising “an epicyclic gearbox comprising a sung [*sic*] gear (111), planetary gears (114), and ring gear (the splines of 111).” Office Action at 4-5. Applicant submits that Moller fails to teach at least these features.

Moller teaches that “[e]ach pin 111 carries a gear wheel 114 which is placed between and engages the two racks 110 and 115.” Moller ¶ 40. For at least four reasons, neither pin 111 nor gear wheel 114 serve the purposes alleged by the Office Action. First, contrary to the Office Action’s assertion, pin 111 cannot serve as a sun gear, because it is not even a gear. Rather, pin 111 serves essentially as an *axle* about which gear wheel 114 rotates. Second, despite the Office Action’s assertion, Moller does not teach that pin 111 includes “splines” that may serve as a ring gear. Indeed, if pin 111 included splines as suggested, gear wheel 114 would be unable to rotate around pin 111. Third, not only does pin 111 not include splines, but also pin 111 cannot possibly serve the dual functions of both a sun gear *and* a ring gear of an epicyclic gearbox as the Office Action suggests. And fourth, the gear wheel 114 of Moller cannot serve as the planetary gear of an epicyclic gearbox. As is well understood in the art and explained in the specification, “the planetary gear(s) travel(s) around the sun gear, whose axis is fixed.” Para. 23. That is, like a planet *revolves* around the sun, so do the planetary gears *revolve* around the sun gear. In Moller, by contrast, gear wheel 114 does not revolve or travel around any sun gear. Rather, gear wheel 114 merely *rotates* around pin 111.

For at least the above reasons, nothing in Moller teaches or suggests a device comprising an epicyclic gearbox, which by definition requires a sun gear, planetary gears, and a ring gear. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

## **VI. Conclusion**

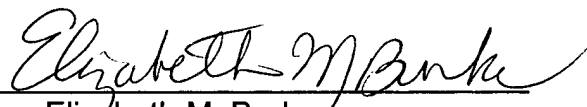
In view of the foregoing amendments and remarks, Applicant submits that the pending claims are not anticipated by the references cited against this application. Applicant therefore requests the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: August 11, 2008

By:   
Elizabeth M. Burke  
Reg. No. 38,758